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| MERCHANT & GOULD PC | | | LEITH, PATRICIA A | |
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DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/810,484

Applicant(s)

PUSHPANGADAN ET AL.

Examiner

Patricia Leith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) 39-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/9/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-83 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-38 in the reply filed on 1/11/06 is acknowledged. The traversal is on the ground(s) that the search for the respective Groups of Inventions would not be burdensome. This is not found persuasive because as indicated in the original Restriction requirement, all of the Groups are Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II and III; this is further evidenced by their different classifications.

Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 39-83 are hereby withdrawn from consideration on the merits as they are directed toward a non-elected invention.

Claims 1-38 were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 states 'wherein plant parts are selected'. The phrase 'plant parts' lacks antecedent basis in claim 1. Further, claim 9 states 'seeds of white and black varieties'. This phrase is ambiguous; does this mean white and black varieties of seeds or plants? The ordinary artisan could not be absolutely certain what Applicant was intending to claim and thus this claim is deemed indefinite.

Correction is necessary.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

It is deemed that the claims are not enabled for certain embodiments such as all extracts and all uses. Additionally, overall, the claims are not enabled because the Specification has not set forth a clear and exact method for making and using the composition of the claims.

First, with regard to the recitation of 'extract' in claims 1 and 5-38, the state of the art is unpredictable with regard to plant extracts. Applicants claim a method for extracting particular phytochemicals from particular fractions of extracted plant matter but do not claim what solvents and chromatography media are used in the initial crude extraction or any of the fractionation steps thus precluding the make or use of these 'extracts' without undue experimentation.

Secondly, it is deemed that the claims are not enabled for all of the uses of treatment as recited by the claims. In particular, it is deemed that Applicant has not provided ample support to verify the assertion that any extracts of *Centella asiatica* and *Sesamum indicum* will treat or prevent amnesia, treat leprosy, cure migraine, treat vertigo, leucoderma and anemia, reduce piles, treat stomachic, reduce enlargement of spleen, act as a diuretic or possess nerve relaxant properties.

Lastly, it is deemed that the skilled artisan could not use the invention without undue experimentation due to the ambiguity present in the Instant specification.

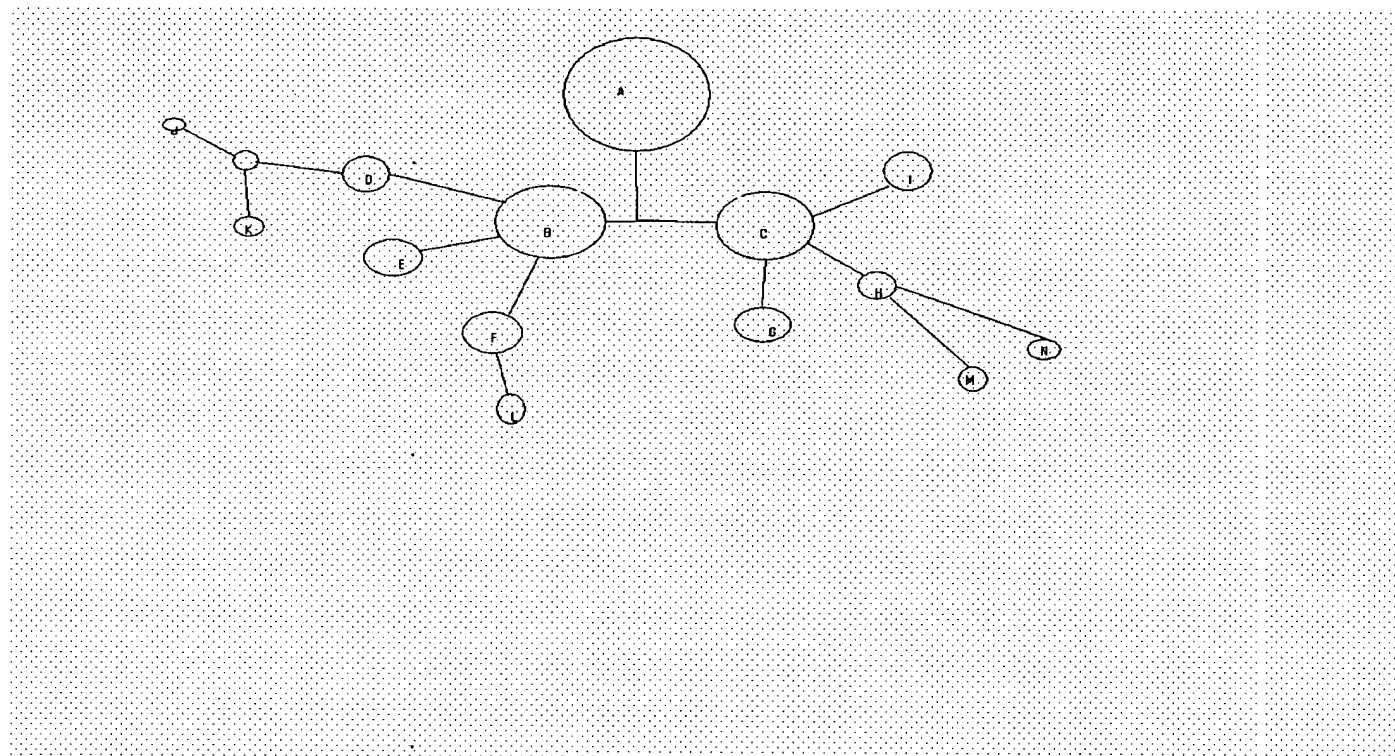
It is well known in the art that polarity of solvents plays a key role in determining the final product obtained by an extraction. However, because many phytochemicals remain undiscovered, the skilled artisan has to make his best educated guess as to what types of phytochemicals will be successfully extracted with a solvent of a particular polarity. Often times, unless the constituents in a particular plant extract have been well evaluated and documented in the literature, the skilled artisan must adhere to trial and error protocols in order to quantitatively determine phytochemical constituents present in samples obtained from respective extraction procedures. These procedures are common when, for example, a plant or part thereof has been documented in the literature as possessing some medicinal quality. The skilled artisan will attempt numerous extraction protocols in attempt to isolate the particular ingredient which has this medicinal quality. Typically, beginning with the first crude extraction, it is a guess as to whether or not the extract will possess certain phytochemical constituents. It is noted that the Instant specification does not disclose what the active ingredient of the extract is; on the contrary, the specification only teaches certain extracts which provide for the effective ingredient.

Each successive extraction of plant matter yields different products due to the exclusion of ingredients based on the polarity of the solvents solvating constituents with similar polarities. Subsequently, the properties of each respective product are unpredictable and would need to be evaluated for chemical constituents. The following is an illustrative example of the many products which may be produced by different

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successive extraction

protocols:



In this example, assume that A= the initial water extract from a homogenized sample of grape. The water extract from the grape is then subjected to a methanol/water extraction to form products B (soluble with methanol) and C (more soluble with water). Product C is then extracted in a separatory funnel with three organic solvents: chloroform, benzene and ethyl ether to form products G, H and I which solvate with the respective solvents based on the polarity of the inherent constituents. Product H, which we will assume is the product obtained in the benzene fraction, is extracted again in a separatory funnel with benzene and methanol to remove any residual methanol-soluble constituents. The additional circles represent extractions

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which may be done to obtain different products, using similar solvents as discussed previously, or entirely different solvents. Consequently, the characteristics of each respective product would need to be evaluated for chemical constituents. This representation is indicative of the vast array of distinct products which may be obtained due to the ***enormity of possible extraction permutations***.

Unpredictability with regard to plant extracts due to their highly complex nature has been well documented in the art. Revilla et al. for example (1998) showed that the ***slightest variations in polarity of solvent and reaction time*** upon grape extraction provided respective products with unique characteristic properties (See Tables 1, 2, 4, 5, 6 and 7). In turn, each product would possess varying pharmacological properties based upon their respective methods of extraction. Further contributing to the unpredictability of plant extracts, it has been determined that in some cases, the active agent is not a single ingredient, but a combination of ingredients working synergistically to provide a therapeutic effect:

"The blood red sap from the bark of several species of Croton (Euphorbiaceae) are used in traditional medicine in S. America to treat wounds and a series of diseases including cancer. More than 90% dry weight of the sap consists of mixtures of proanthocyanidins ranging from monomers to heptamers and even to polymers of twenty units. We have established the chemical structures of these oligomers and the monomeric units are either catechin or galocatechin... In addition, we isolated some novel diterpenoids and a series of simple phenols as minor constituents. As a result of biological tests we have

concluded that here is no single ingredient for would healing but than the whole sap contributes to the healing process" (Phillipson, J. 1999).

It is the opinion of the Examiner, in light of the grave unpredictability in the art with regard to plant extracts, that Applicant is not enabled for any extract as Instantly claimed. Each product obtained from an extraction is unpredictable in nature. Even the most skilled of artisans would need to quantify each product for constituents as well as medicinal efficacy. Considering this evidence, the skilled artisan, lacking information with regard to any other solvents which will produce the Instantly claimed phytochemicals, would necessarily need to perform tedious trial and error protocols without expectation of success in order to ascertain what other extracts would provide for the specific therapeutic uses as described in the specification.

Again, it is deemed that the claims are not enabled for all of the uses of treatment as recited by the claims. In particular, it is deemed that Applicant has not provided ample support to verify the assertion that any extracts of *Centella asiatica* and *Sesamum indicum* will treat or prevent amnesia, treat leprosy, cure migraine, treat vertigo, leucoderma and anemia, reduce piles, treat stomachic, reduce enlargement of spleen, act as a diuretic or possess nerve relaxant properties.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

The Wands factors were addressed *supra*. The state of the art reflects that there are no cure for ailments such as amnesia and leprosy, migraine, vertigo, leucoderma, piles, stomachic and enlargement of the spleen and such ailments are difficult to treat. Applicant has not provided any indication that the composition of the claims would be even relatively effective in treating these diseases. Further, although Applicant has shown that memory in mice improved upon ingestion of a composition comprising *Centella asiatica* and *Sesamum indicum*, it is not known what composition was actually given to the mice (see *infra*).

Further, it is deemed that the skilled artisan could not use the invention without undue experimentation for the following reason. It is unclear in the Specification exactly what extracts are actually shown to have some medicinal effect. For example, page 11 of the Instant specification teaches that both *Centella asiatica* and *Sesamum indicum*

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are extracted with a mixture of alcohol and water (see bottom of page). However, it is unclear what extracts are actually used in the experiments, because the plant matter which is later referred to as 'Sesamum oil' or 'oil extract'. An alcoholic/water (A/W) extract of the plant material would necessarily extract polar, water-soluble matter from the plant material. Why is the specification referring to this extract as 'oil'? Is the oil being used instead of the A/W extract? It is not clear in the Specification what is being used in the experiments and if an 'oil extract' was used and found to be efficacious, there is no teaching in the Instant specification of how the oil extract is produced.

The present Specification fails to teach the worker of ordinary skill in the art how to make and practice the instantly claimed method for, in that the Specification fails to provide a full, clear and exact description of the claimed Invention. The worker of ordinary skill in the art would not be able to practice the invention as claimed absent undue experimentation, given the limited and incomplete description set forth in the Specification.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently

supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Claims 1 and 5-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 5-38 recite the term 'extract' of *Centella asiatica* and *Sesamum indicum*. It is deemed that Applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number of extracts.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to *all* extracts. The possible variations of extracts are limitless. Although Applicant has disclosed several extracts of *Centella asiatica* and *Sesamum indicum*, this disclosure is actually a *very few* number in comparison to the enormous, *potentially millions* of types of extracts which could be obtained from *Centella asiatica* and *Sesamum indicum*. The reason for this large amount of permutations is because extraction techniques are often coupled in order to obtain a product; for example

1) a water extraction followed by an alcoholic extraction: the product obtained is an extract.

2) a supercritical extraction (CO₂) followed by an alcoholic and then a non-polar solvent extraction (e.g., chloroform): the product is an extract.

3) a benzene extraction followed by a water extraction and chromatographic separation: the product is an extract.

4) a water/chloroform extraction (e.g., in a separatory funnel), followed by collection of the water layer, chromatographic separation and crystallization of an isolate: the product is an extract.

5) squeezing the plant to obtain a juice: the product is an extract.

6) dipping the plant in an organic solvent to remove the waxy layer: the product is an extract.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.' *Lockwood v. American Airlines, Inc.*, 107 F. 3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F. 2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas,

etc., that set forth the claimed invention.” Lockwood, 107 F. 3d at 1572, 41 USPQ2d at 1966.” Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398. The specification lacks sufficient variety of species of extracts to reflect this variance in the genus since the specification does not provide sufficient examples of such a genus of extracts.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”) Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of ‘extract’ and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the entire scope of the claimed invention and thus, this rejection is proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 7, 8 and 10–38 are rejected under 35 U.S.C. 102(b) as being anticipated by Pletcher, B. (1998).

Pletcher, B. reported that an ancient foot – massage composition from India includes gotu kola (*Centella asiatica*) leaf extract and sesame oil (see p. 1). Pletcher, B. makes it clear that the natural remedy is obtained via boiling the gotu kola leaf in sesame (*Sesamum indicum*) oil (p. 1). It is known in the art that boiling plant matter in oil will extract the oil components of the plant (like dissolves like). Thus, it is deemed that the foot-massage oil as reported by Pletcher contained sesame oil as well as gotu kola oil. The foot-massage oil as reported by Pletcher is considered a syrup or elixir (as required by claim 7). Further, sesame oil is produced from black and white sesame seeds (see for example IndianGyan.com, pages 1-2).

Claims 6 and 10-38 merely recite inherent properties of the composition, and therefore do not materially change the composition for the sake of patentability.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pletcher, B. (1998).

The teachings of Pletcher were discussed *supra*.

Pletcher did not specifically teach wherein the foot-massage oil contained carriers such as sucrose or sodium chloride for example or the specific percentages of oils as required by claims 2-4.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

One of ordinary skill in the art would be motivated to combine the oil composition as disclosed by Pletcher with a carrier such as sucrose or sodium chloride for example because 1) carriers such as these would have offered a preservative effect to the oil composition, and 2) addition of carriers to the oil composition would have thickened the oil composition to a more viscous consistency, thereby creating a product which would stay on the skin longer and hence, provide lasting therapeutic benefits.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

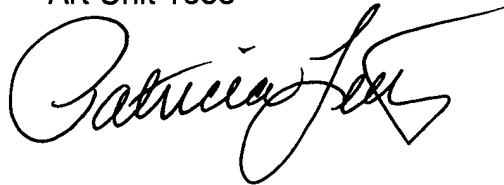
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a stylized flourish at the end.

02/04/06